K092150

BIOMET
MANUFACTURING CORP.

OCT 2 7 2009

510(k) Summary

Preparation Date: July 15, 2009

Applicant/Sponsor: Biomet Manufacturing Corp.

Contact Person: Susan Alexander

Proprietary Name: Cobalt™ MV with Gentamicin Bone Cement (also known as Cobalt™ G-MV)

Common Name: PMMA Bone Cement

Classification Name: Polymethylmethacrylate (PMMA) Bone Cement (21 CFR §888.3027)

Product Code: MBB (bone cement, antibiotic), LOD (bone cement)

Legally Marketed Devices to Which Substantial Equivalence is Claimed:

Cobalt™ G-HV Bone Cement	K051532	Biomet Manufacturing Corp.
Simplex® P with Tobramycin Bone Cement	K014199	Stryker Howmedica Osteonics

Device Description: Cobalt™ G-MV Bone Cement is a methyl methacrylate-styrene copolymer based acrylic medium viscosity bone cement with gentamicin. Cobalt™ G-MV Bone Cement provides two separate, pre-measured sterilized components that when mixed form rapidly-setting radiopaque bone cement for use in orthopedic surgery.

Intended Use: Cobalt™ G-MV Bone Cement is an acrylic cement-like substance which allows seating and fixation of the prosthesis to the bone. After complete polymerization, the cement acts as a buffer for even weight distribution and other stresses between the prosthesis and the bone.

Indications for Use: Cobalt™ G-MV Bone Cement is indicated for use as bone cement in arthroplasty procedures of the hip, knee and other joints to fix plastic and metal prosthetic parts to living bone when reconstruction is necessary because of revision of previous arthroplasty procedures due to joint infection. The cement is intended for use to affix a new prosthesis in the second phase of a two-stage revision after the initial infection has been cleared.

Summary of Technologies: The technological characteristics of Cobalt™ G-MV Bone Cement are the same as, or similar to, the predicate devices.

Non-Clinical Testing: Non-clinical laboratory testing was performed to determine substantial equivalence. The results indicated that the device was functional within its intended use.

Clinical Testing: None provided as a basis for substantial equivalence.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Biomet, Inc.
% Ms. Susan Alexander
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581

OCT 2 7 2009

Re: K092150
Trade/Device Name: Cobalt™ MV with Gentamicin (aka Cobalt™ G-MV) Bone Cement
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: II
Product Code: LOD, MBB
Dated: October 7, 2009
Received: October 8, 2009

Dear Ms. Alexander:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):_____

Device Name: Cobalt™ MV with Gentamicin (aka Cobalt™ G-MV) Bone Cement

Indications For Use:

Cobalt™ MV with Gentamicin Bone Cement is indicated for use as bone cement in arthroplasty procedures of the hip, knee and other joints to fix plastic and metal prosthetic parts to living bone when reconstruction is necessary because of revision of previous arthroplasty procedures due to joint infection. The cement is intended for use to affix a new prosthesis in the second phase of a two-stage revision after the initial infection has been cleared.

Prescription Use X AND/OR Over-the-Counter Use NO
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092150